REMARKS

With the entry of the above amendments, claims 56-73 are pending in this application. Applicant has cancelled the previously pending claims and added claims 56-73. Support for newly added claim 56 is found in originally filed claims 1, 9 and 10. Support for claim 57 is found in originally filed claim 3. Support for claim 58 is found in originally filed claim 6. Support for claim 59 is found in originally filed claim 7. Support for claim 60 is found in originally filed claim 8. Support for claim 61 is found in originally filed claim 15. Support for claim 62 is found in originally filed claim 16. Support for claim 63 is found in originally filed claim 9. Support for claim 64 is found in originally filed claim 11. Support for claim 65 is found in originally filed claim 12. Support for claim 66 is found in originally filed claim 13. Support for claim 67 is found in originally filed claim 21. Support for claim 68 is found in originally filed claim 22. Support for claim 69 is found in originally filed claim 23. Support for claim 70 is found in originally filed claim 24. Support for claim 71 is found in originally filed claim 25. Support for claim 72 is found in originally filed claim 27. Support for claim 73 is found in originally filed claim 28. Applicant submits that no new matter has been added by these amendments.

Claims 1, 3-8, 9-34 and 42-55 stand rejected under 35 USC § 112, first paragraph as not being enabled by the specification. Claims 1, 3-6, and 10 stand rejected under 35 USC § 102 over U.S. Patent No. 5,798,345 issued to Knutson et al. (hereinafter "Knutson"). Lastly, claims 1, 3-8, 9-34 and 43-55 stand rejected under 35 USC § 101 as claiming the same invention as U.S. Patent No. 6,503,893 issued to Bishop et al. (hereinafter "Bishop"). Applicant traverses these rejections for at least the reasons presented below.

Rejections under 35 USC § 112, first paragraph

Claims 1, 3-8, 9-34 and 42-55 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabling. The Examiner asserts that the specification does not enable one skilled in the art to practice the invention commensurate with the scope of the claims. The gravamen of the Examiner's rejection appears to be that a) there are too many compounds within the claimed genus and too many malignant cells associated with cancers, b) compounds within the claimed genus may act differently on different cells, c) one could not predict in advance which of the recited species would be active for a particular hyperproliferative cell, and d) it would require ""undue experimentation" to practice the invention.

With respect to the recitation of a genus of compounds (e.g., formula III of the present application), the MPEP (see § 2164.02) requires that representative examples together with a statement applicable to the genus as a whole is sufficient if understood by one of ordinary skill in the art. There is no requirement for any working examples or any specific number of working examples. It is respectfully submitted that the extensive disclosure of active vitamin D compounds in the specification at pages 11 and 12 is more than adequate to support the genus of vitamin D compounds recited in claim 56.

Whether or not the mechanism of action of the active vitamin D compounds is unknown does not in itself provide support for an assertion that the art worker would not be able to reasonably predict that the claimed invention would be operable. It is not disputed that the active vitamin D compounds may vary in their ability to inhibit hyperproliferation of malignant or neoplastic cells. However, there is no requirement that all of the compounds within a claimed genus exhibit the same degree of efficacy in order to meet the requirements of § 112.

Satisfaction of the enablement requirement of § 112 is not precluded by the necessity of some experimentation, such as routine screening. The key word is "undue", not

"experimentation." A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

The Examiner is respectfully requested to note that the metes and bounds of the class of vitamin D compounds recited by the present claims is well-delineated and that working examples are provided which would enable the art worker to obtain and employ these compounds as broadly as they are claimed. It is well-settled that it is not necessary that a patent applicant test all embodiments of his/her invention to meet the requirements of § 112. The fact that bioassays would have to be conducted to determine the level of activity of a given compound within the scope of the claims with respect to a particular cell species does not constitute "undue experimentation" particularly in an art where the level of skill is so high.

It is respectfully submitted that § 112(1) requires no more than a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, and this requirement has clearly been met.

Moreover, Applicant directs the Examiner's attention to the literature on the treatment of hyperproliferation of cells and/or cancers, tumors, etc. and vitamin D compounds. For example, *in vitro* assays using 1,25 dihydroxyvitamin D or its analogues demonstrated antiproliferative effects in cell lines derived from many malignancies including adenocarcinomas of the prostate (*Molec. and Cell. Endocrinology* 126:83-90, 1997; *Proc. Amer. Assoc. Cancer Res.* 38:456, 1997; *J. Ster. Biochem. and Molec. Biol.* 58:277-288, 1996; *Endocrinology* 137:1551561, 1996; *Endocrinology* 136:20-26, 1995; *Cancer Research* 54:805-810, 1994; *Endocrinology* 132:1952-1960, 1993; and *Anticancer Research* 14:1077-1081, 1994), breast (*Proc. Amer. Assoc. Cancer Res.* 38-456, 1997; *Biochemical Pharmacology* 44:693-702, 1992); colon (*Biochemical and Biophysical Research*

Communications 179:57-62, 1991; *Archives of Pharmacology* 347:105-110, 1993); pancreas (*British Journal of Cancer* 73:1341-1346, 1996); and endometrium (*Journal of Obstetrics and Gynaecology Research* 22:529-539, 1996); lung (*Anticancer Research* 16:2953-2659, 1996); myeloid leukemia (*PNAS USA* 78:4990-4994, 1981); melanoma (*Endocrinology* 108:1083-1086, 1981); and sarcomas of the soft tissues (*Annals of Surgical Oncology* 3:144-149, 1996) and bone (*Journal of the Japanese Orthopaedic Association* 69:181-190, 1995). Studies in animals have shown antiproliferative activity of Vitamin D or its analogues in prostate cancer (*Urology* 46:365-369, 1994); breast cancer (*J. NCI* 89:212-218, 1997; *Lancet* 1:188-191, 1989); squamous cell carcinoma (*Molecular and Cellular Differentiation* 3:31-50, 1995); myeloid leukemia (*Blood* 74:82-93, 1989 and PNAS USA 80:201-204, 1983) and retinoblastoma (*Archives of Opthalmology* 106:541-543, 1988; *Archives of Opthalmology* 106:536-540, 1988).

Applicant's application sets forth the specific examples relating to the treatment of prostate cancer (examples 1-3, 6-11 and 13-14), retinoblastoma (example 16), and liver cancer (example 17).

Applicant respectfully submits that the pending claims fully meet all the requirements of § 112, and that the rejection be reconsidered and withdrawn.

Applicant would also like to point out that the Examiner has referred to the ability of the presently claimed compounds to "prevent" all cancers claimed in claim 3. With due respect, Applicant has not claimed "preventing" cancers, but has claimed, as recited in claim 56, "inhibiting the hyperproliferation of malignant or neoplastic cells."

Rejections under 35 USC § 102

Claims 1, 3-6, and 10 stand rejected under 35 USC § 102 over Knutson. While claims 1, 3-6 and 10 have been cancelled, rendering this rejection moot, Applicant wishes to point out that the currently pending claims are not anticipated by the Knutson reference for at least

the following reasons. The Knutson reference fails to disclose a method of inhibiting hyperproliferation of malignant or neoplastic cells with an active vitamin D compound "wherein the amount of active vitamin D is a high dose which is between about 10μg to about 200μg/dose given once per week to once every 12 weeks" (see claim 56). As this limitation is shared by all of the pending claims, the Knutson reference fails to anticipate claims 56-73 of the application.

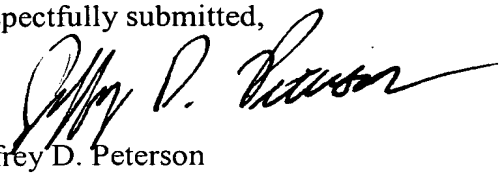
Rejections under 35 USC § 101

Claims 1, 3-8, 9-34 and 43-55 stand rejected under 35 USC § 101 as claiming the same invention as claims 1-44 of Bishop. While claims 1, 3-8, 9-34 and 43-55 have been cancelled, rendering this rejection moot, Applicant wishes to point out that the currently pending claims are not the same as those of the Bishop patent for at least the following reasons. All of the pending claims contain the limitation of treating cells with an active vitamin D "wherein the amount of active vitamin D is a high dose which is between about 10μg to about 200μg/dose given once per week to once every 12 weeks" (see claim 56). The Bishop patent fails to claim or disclose such a limitation. As the Bishop patent fails to claim such a limitation, the Bishop patent cannot serve as the basis of a double patenting rejection of the presently pending claims of the application.

SUMMARY

Based on the foregoing, Applicant respectfully submits that the present application is in condition for allowance, and a favorable action thereon is respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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